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United States v. Dotterweich, 320 U.S. 277, 280 (1943).

The tobacco industry's theory would frustrate these public health purposes. If promotional claims alone determined the "intended use" of a product, a manufacturer could market a potent tranquilizer solely for its "pleasurable" effect or an amphetamine for its "energizing" effect and avoid the Act's reach. The same manufacturer could coat the tranquilizer or amphetamine with sugar, advertise it for its "taste and flavor," and again escape FDA regulation. It is not hard to imagine a manufacturer of a generic version of Prozac, an antidepressant drug currently approved by FDA and available only by prescription, who would seek to avoid FDA regulation by advertising its product as intended solely for the "pleasure" of its consumers. If these products could so easily escape FDA regulation, the public health would be endangered.

These examples are not purely hypothetical. As discussed above, manufacturers of imitation cocaine or "caine" products, which contain anesthetic drugs such as lidocaine, have attempted to avoid FDA regulation by selling their products as "incense." Although FDA has successfully asserted jurisdiction over these products in the past, the Agency could be precluded from doing so under the manufacturers' legal theory.

New evidence received during the comment period provides another example of the possible results if the Agency accepted the manufacturers' legal theory. In 1992, the British American Tobacco Company (BATCO), the parent company of Brown & Williamson Tobacco Corporation, considered purchasing a manufacturer of nicotine patches, Stowic Resources Ltd., because "[t]here is currently a void in the market for a product that provides tobacco satisfaction in a form that is acceptable and available to

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many segments of the market.”¹¹¹² The purchase was ultimately rejected after BATCO and Brown & Williamson researchers found that nicotine patches did not provide the consumer with “[t]he rapid, peaking intake of nicotine which the smoker clearly wants.”¹¹¹³ Under the manufacturers’ theory, however, it would nonetheless be legally permissible for BATCO and Brown & Williamson to sell high-potency nicotine patches or any other product whose sole purpose was to deliver pharmacologically active doses of nicotine without FDA regulation so long as the manufacturers claimed to market the products exclusively for “tobacco satisfaction.”

For sound policy reasons, the Agency must be able to look beyond a manufacturer’s promotional claims when determining whether to regulate a product that contains a known drug or that has known pharmacological uses. Where manufacturers avoid promoting the pharmaceutical uses of products that contain drug ingredients or where manufacturers deliberately make ambiguous claims or otherwise seek to obscure the true nature of their products, FDA must be free to consider other objective evidence to establish the true intended use of the product. As discussed in sections II.A.1., II.B.1., and II.C.1., above, this other objective evidence may include the product’s foreseeable pharmacological effects and uses, actual consumer use, and the statements, research, and actions of manufacturers.

¹¹¹² Brown & Williamson, *Transdermal Nicotine Patches* (1992), at 3. See AR (Vol. 531 Ref. 124).

¹¹¹³ Kausch, Research and Development/Quality, *Transdermal Nicotine* (1992). See AR (Vol. 531 Ref. 124).

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2. Consideration of Tobacco Manufacturers' Promotional Claims Supports the Agency's Position

The Agency also disagrees with the premise of the tobacco industry's position—namely, that consideration of their promotional claims will demonstrate that cigarettes and smokeless tobacco products are not intended to affect the structure or function of the body. In fact, consideration of the claims made in tobacco advertising lends support to the Agency's determination that cigarettes and smokeless tobacco are “intended” to affect the structure and function of the body.

Several comments on the Jurisdictional Analysis urge FDA to consider the promotional claims of the tobacco manufacturers in determining whether the manufacturers intend to affect the structure or function of the body. The comments of the American Society of Addiction Medicine, for example, assert that consideration of promotional claims provides further support for the finding that tobacco manufacturers intend to affect the structure and function of the body. Conversely, the tobacco industry comments maintain that consideration of these claims will show that the manufacturers do not intend to affect the structure or function of the body.

The Agency agrees that promotional claims can be relevant evidence of intended use. *See* section II.E.1., above. As the tobacco industry comments recognize, these claims can be of two types, implied or express.¹¹¹⁴ Express claims for a product overtly promote the product's effects on the structure or function of the body. Implied claims

¹¹¹⁴ Joint Comments of the Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. II, at 91. *See* AR (Vol. 535 Ref. 96) (“the determining factor is claims—implied or expressed—made in marketing the product”) (emphasis added). *See also* section 201(n) of the Act (21 U.S.C. 321(n)) (in determining whether labeling or advertising is misleading the Agency must consider both the representations “made” and the representations “suggested” by the manufacturer).

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suggest, but do not explicitly recommend, pharmacological use. The courts have recognized that implied drug claims can make a product a drug even in the presence of express disclaimers warning against drug use. For instance, in a case involving an imitation cocaine product sold as incense and advertised as not for drug use, the Ninth Circuit held:

The fact that the items were called “incense” and advertised as “Not for drug use” cannot be controlling on the issue of whether they are drugs. Where, as here, the items are otherwise promoted and advertised in ways that *suggest* they are cocaine substitutes, [the vendor’s] intent in distributing the products is clear. Self-serving labels cannot be allowed to mask the vendor’s true intent as indicated by the overall circumstances.

United States v. Storage Spaces Designated Nos. “8” and “49,” 777 F.2d 1363, 1366 n.5 (9th Cir. 1985) (emphasis added), *cert. denied*, 479 U.S. 1086 (1987).

As suggested in the comments, the Agency has examined the promotional claims of the tobacco manufacturers. Although recent tobacco product advertisements do not make express drug claims, the implied pharmacological claims in some tobacco advertisements provide additional support for the Agency’s finding of intended pharmacological use. In particular, as described below, advertisements that promise that tobacco products will provide “satisfaction” suggest to the consumer that use of tobacco products will provide desired pharmacological benefits, including satisfying addiction.

The use of “satisfaction” claims in tobacco product advertising is common. Since the 1970’s, most major tobacco manufacturers have used advertising campaigns that promote “satisfaction.” For instance, the R.J. Reynolds Tobacco Company (RJR) has used a promise of “satisfaction” to advertise many cigarette brands, including Camel

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Lights, Salem, Real, More, and Now.¹¹¹⁵ A 1990 advertisement for Now brand cigarettes, for example, asks “Can a cigarette have just 2 mgs of tar and still be satisfying to smoke? . . . NOW can.”¹¹¹⁶ Likewise, “satisfaction” claims have been used by Brown & Williamson, Lorillard, and Liggett & Myers.¹¹¹⁷ In one typical, recent advertisement, Lorillard promoted its True brand with the slogan “The Lowest with True *Satisfaction* . . . True *Delivers*.”¹¹¹⁸ Some of these advertisements distinguish “satisfaction” from taste. For example, a Brown & Williamson advertisement for Barclay states:

If your ultra light is ultra boring, why do you still smoke it?
Because you probably think that’s the sacrifice you have to make.
Well, not any longer. We’ve just made ultra lights you don’t have
to make any sacrifices for. At least not on taste. *And not on
satisfaction.*¹¹¹⁹

Smokeless tobacco manufacturers also rely on “satisfaction” claims in advertising. The nation’s largest smokeless tobacco manufacturer, United States Tobacco Company (UST), has used satisfaction promises to advertise several brands, including Copenhagen,

¹¹¹⁵ See Tobacco Advertisements, in American Society of Addiction Medicine, Comment (Dec. 29, 1995), appendix 6, at 89-90, 92, 94-96, 98. See AR (Vol. 528 Ref. 97).

¹¹¹⁶ *Id.* at 98.

¹¹¹⁷ *Id.* at 82-86, 88, 91, 97, 99.

¹¹¹⁸ *Id.* at 99 (emphasis added).

¹¹¹⁹ *Id.* at 97 (emphasis added).

In addition to differentiating between taste and satisfaction in the quoted passage, this advertisement also uses the term “satisfying” in a subsequent passage to describe the flavor of Barclay, stating that “[w]e gave Barclay a new blend of tobaccos for a smoother, more satisfying flavor.” *Id.* This dual usage of satisfaction occurs in other advertisements. For instance, in an advertisement for Camel Lights, RJR uses satisfaction both as an independent attribute of its product (promising “All the flavor *and satisfaction* that’s been missing in your low tar cigarette”) and as an adjective to describe the product’s taste (promising “a rich, rewarding, truly satisfying taste”). *Id.*, at 95 (emphasis added).

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Skoal, and Happy Days.¹¹²⁰ In fact, the slogan “It Satisfies” is the signature of UST’s Copenhagen brand and appears on the lid of each package.¹¹²¹

The tobacco industry argues that “satisfaction” is not an implied drug claim. In its view, “satisfaction” is not a euphemism for the consumer’s pharmacological response to nicotine. Rather, as one cigarette manufacturer commented, “[s]atisfaction’ . . . reflects the consumer’s total reaction to the total smoking experience delivered by the cigarettes.”¹¹²²

The Agency agrees that the term “satisfaction” reflects the consumer’s reaction to the experience of smoking a cigarette or using smokeless tobacco. Indeed, it is precisely for this reason that the Agency finds that the use of the term to promote cigarette and smokeless tobacco is an implied drug claim.

The meaning of a promise of “satisfaction” depends upon the needs or expectations of the consumer. A “satisfying” meal means something quite different from a “satisfying” movie, which in turn means something different from a “satisfying” driving experience. A product that is satisfying to consumers is one that fulfills the needs or expectations of the consumer. Thus, a “satisfying” meal must meet the consumer’s desires for taste and nutrition, while a “satisfying” driving experience must meet the consumer’s desires for power, maneuverability, and comfort.

¹¹²⁰ *Id.* at 93, 100-101.

¹¹²¹ *Id.* at 100.

¹¹²² Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 8. *See* AR (Vol. 529 Ref. 104).

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In the case of cigarettes and smokeless tobacco, a “satisfying” product must meet the consumer’s motivations for using the product. As discussed in sections II.A. and II.B., above, these motivations are primarily pharmacological. Most users of tobacco products are addicted to nicotine. They use cigarettes and smokeless tobacco to satisfy their addiction and to obtain other pharmacological effects, such as anxiety reduction or stimulation. To these users, a manufacturer’s promise of “satisfaction” implies that the product will fulfill their craving for the pharmacological effects of nicotine—satisfying their addiction and providing the sought-after mood-altering effects of nicotine.

The tobacco industry’s internal documents themselves show that consumer “satisfaction” is intimately connected to nicotine’s pharmacological effects and that the tobacco manufacturers know this. The internal company documents that have recently become publicly available show that for the past three decades, tobacco industry officials have consistently expressed the view that nicotine’s pharmacological effects are essential to consumer satisfaction.

Officials at Brown & Williamson and its parent company, the British American Tobacco Company (BATCO), for instance, have consistently linked nicotine delivery to consumer satisfaction. Thus, BATCO scientists have stated:

- “Nicotine has well documented pharmacological action. . . . *It is believed to be responsible for the ‘satisfaction’ of smoking*, using this term in the physiological rather than the psychological sense.”¹¹²³
- “*The basic assumption is that nicotine . . . is almost certainly the key smoke component for satisfaction*”¹¹²⁴

¹¹²³ Wood DJ, BATCO Group Research and Development, *Aspects of the R&DE Function*, notes for a talk given at Chelwood, Sep. 1969 (Jul. 20, 1970), at 7 (emphasis added). See AR (Vol. 22 Ref. 287).

¹¹²⁴ BATCO Group R&D Research Conference, Rio de Janeiro, Brazil (Aug. 22-26, 1983), at 10 (emphasis added). See AR (Vol. 179 Ref. 2087).

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- “[N]icotine . . . probably provides the basis of smoking satisfaction.”¹¹²⁵
- “[I]n its simplest sense puffing behavior is the means of providing nicotine dose in a metered fashion.”¹¹²⁶
- “Intuitively it is felt that ‘satisfaction’ must be related to nicotine. Many people believe it [is] a ‘whole body response’ and involves the action of nicotine in the brain.”¹¹²⁷

Other industry officials have expressed the same view. For example:

- Senior RJR scientists have written that “the confirmed user of tobacco products is primarily seeking the physiological ‘satisfaction’ derived from nicotine”¹¹²⁸ and that “the ultimate satisfaction comes from the nicotine which is extracted . . . in the lungs.”¹¹²⁹

¹¹²⁵ BATCO, Proceedings of the Smoking Behaviour Marketing Conference, Session I slides (Jul. 9-12, 1984) (emphasis added). See AR (Vol. 21 Ref. 238).

¹¹²⁶ *Id.*

¹¹²⁷ BATCO, *Nicotine Conference Outline* (Jun. 6-8, 1984) at BW-W2-01977 (emphasis added). See AR (Vol. 22 Ref. 290).

The record contains numerous other similar BATCO and Brown & Williamson statements. For example, as part of their evaluation of whether BATCO should purchase a manufacturer of nicotine patches, Brown & Williamson researchers in 1992 stated that “[t]he fact that people use snuff and chewing tobacco indicates that administration routes [of nicotine] other than inhalation can deliver tobacco satisfaction.” *Transdermal Nicotine Patches*, at 3 (emphasis added). See AR (Vol. 531 Ref. 124).

Similarly, as part of Project Wheat, BATCO researchers reported that “there is evidence of a conflict between concern for health and the desire for a satisfying cigarette, from which it follows that low tar brands would be much more widely accepted if their nicotine deliveries could be brought within the range required by groups of consumer[s].” Wood DJ (BATCO), *Project Wheat -- Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Deliveries as Influenced by Inner Need* (Jan. 30, 1976), at 48 (emphasis added). See AR (Vol. 20 Ref. 204-2).

¹¹²⁸ Teague CE, R.J. Reynolds, *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 1 (emphasis added). See AR (Vol. 531 Ref. 125).

Teague also wrote that “what we are really selling [is] nicotine satisfaction.” *Id.* at 5 (emphasis added).

¹¹²⁹ Senkus M (R.J. Reynolds Tobacco Co.), *Some effects of smoking (1976/1977)*, at 9 (emphasis added). See AR (Vol. 700 Ref. 593).

Senkus also wrote that “a zero nicotine cigarette . . . really has no potential to provide smoking satisfaction. It produces no taste in the mouth, but even more seriously it fails to provide the ultimate satisfaction in the lungs.” *Id.* at 9 (emphasis added).

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- William Farone, the former Philip Morris director of applied research, has written that “[t]he objective of industry scientists and product developers, simply stated, was *to provide the consumer with the . . . pharmacological satisfaction derived from nicotine. . . .*”¹¹³⁰
- The senior vice president for marketing at UST has written that “[v]irtually all tobacco usage is based upon nicotine, ‘the kick’, satisfaction.”¹¹³¹

Indeed, tobacco manufacturers have even conducted opinion surveys that show that tobacco users understand that their “satisfaction” is based on nicotine. For instance, an affiliate of Brown & Williamson reported that “[m]ost respondents, with a bias toward men, realised that *nicotine* was the attribute in cigarettes causing addiction. It was also usually seen as *the component providing satisfaction.*”¹¹³²

These statements show that, when consumers use cigarettes and smokeless tobacco, their degree of “satisfaction” is closely related to the pharmacological effects of nicotine delivered by the product. The statements also show that tobacco manufacturers have long been aware of the central role of nicotine in consumer satisfaction. In effect, the

¹¹³⁰ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 7 (emphasis added). See AR (Vol. 638 Ref. 2).

¹¹³¹ Testimony of Erik Lindqvist, *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.D. Ok. Jun. 5, 1986) transcript of jury trial proceedings, at 1662 (emphasis added). See AR (Vol. 22 Ref. 292). In another document describing Skoal Bandits, UST states:

The nicotine contents are more or less equivalent to that of a good quality cigarette. The nicotine is absorbed, *giv[ing] satisfaction to the smoker.*

Potential Questions and Answers, submitted in *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.D. Ok. 1986) (emphasis added). See AR (Vol. 30 Ref. 509).

¹¹³² *Attitudes Towards Smoking and Health*, attached to letter from Johnston AH (market research manager, Carreras Rothmans Ltd.) to Bentley HE (Imperial Tobacco Ltd.) (Jul. 26, 1979), at 12 (emphasis added). See AR (Vol. 21 Ref. 218).

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statements establish that the manufacturers use “satisfaction” as a code-word for the pharmacological effects of nicotine.

The Agency has reviewed the manufacturers’ promotional claims and finds that they are consistent with—and in fact provide further support for—the Agency’s conclusion that cigarettes and smokeless tobacco are “intended” to affect the structure and function of the body. When manufacturers of an addictive and psychoactive product use words like “satisfaction” in their advertisements, the word takes on special connotations to the consumer. The advertisements make an implicit pharmacological appeal and hence become further evidence that the products are intended to affect the structure and function of the body.

3. Response to Additional Comments on Legal Theory

The discussion in sections II.A.-E.2., above, has responded to many of the major comments regarding the Agency’s legal analysis of intended use. In this section, the Agency responds to additional comments of the manufacturers and others on this issue.

a. General Comments

1. The tobacco industry contends that the legislative history of the Federal Food, Drug, and Cosmetic Act conflicts with the Agency’s interpretation of the Act and shows that Congress determined that only promotional claims can be considered in determining whether a product is “intended to affect the structure or any function of the body.”

The Agency has carefully reviewed the legislative history of the Act and concludes that it fails to support the tobacco industry’s position. Indeed, what little legislative